

REMARKS

The foregoing Preliminary Amendment and Remarks which follow are in response to the second, final Office Action mailed May 16, 2000, in relation to the parent application, namely, United States Patent Application Serial No. 09/197,938 entitled "System and Method for Securing Sutures to Bone and Tissue", issued as U.S. Patent No. 6,200,330 B1. In that Office Action, the drawings were objected to insofar as Figures 3, 4, 5a, and 5b failed to reflect that the same depicted prior art. With respect to the claims, Claims 1-8, 12, 29, 30 were rejected under 35 U.S.C. §102(b) as being anticipated by Akopov et al. (i.e., U.S. Patent No. 5,242,457). Such Office Action did indicate, however, that Claims 9 and 10 would be allowable if re-written in an independent form to include all the limitations of the base claim and any intervening claims. By way of Applicant's amendment dated July 25, 2000, Applicant sought to seek allowance of Claims 9 and 10, which are the subject of the issued parent application.

By this amendment, Applicant herein responds to the rejection of the claims under 35 U.S.C. §102(b) as being anticipated by the Akopov et al. reference. Specifically, Applicant has cancelled the five originally submitted claims and has submitted herewith new Claims 6-38, which are drawn to both devices and methods for securing sutures, grafts, synthetic materials, and soft tissue or to bone or soft tissue. Such claims are further directed to certain novel embodiments disclosed in the present continuation-in-part application.

With regard to the newly submitted claims, Applicant respectfully submits that the Akopov et al. reference neither teaches nor suggests the novel devices and methods as claimed therein. Specifically, Akopov et al. does not teach nor disclose a surgical implant having a single piton member designed to be directly embedded into bone or soft tissue, as per the devices as claimed in Claims 31 - 43, in this regard, the Akopov et al. reference is specifically directed to surgical staples having opposed prongs which must be stapled into position via a manual instrument (See e.g., Figures 31, 32; column 2, lines 57-65).

The present invention, in contrast, utilizes a single piton element that is further manually positionable into the bone or soft tissue. As such, the implants of the present invention, as claimed

in Claims 35-43, are not only of simpler construction, but are substantially easier to deploy. In support of such novel and unobvious features, there is submitted herewith declarations of Dr. Tom Thomas, Dr. Stephen DeSantis, and Dr. Theodore Benderev, submitted pursuant to 37 C.F.R. §1.132, to emphasize the novelty of such features.

Similarly, the Akopov et al. reference neither teaches nor discloses surgical implant devices including at least one piton member extending therefrom and an attachment member formed thereon such that strain imparted to such attachment member causes said piton member to advance toward the pathway of penetration. In this respect, the Akopov et al. staples are neither manually insertable at a target site nor include outwardly extending piton members and an attachment member oriented in such way such that tension applied to the attachment member causes the piton members to advance into the tissue of the target site. Rather, Akopov et al. discloses a continuous wire staple that at best is hooked into the tissue and simply remains embedded therein. As such, in light of lacking such structural elements, Applicant respectfully submits that such reference does not anticipate nor teach the subject matter for the invention as claimed. (See, e.g., Connell v. Sears, 722 F.2, 1542 (Fed. Cir. 1994). (Anticipation requires the presence of a single prior art disclosure of all elements of a claimed invention arranged as in the claim. Page 1548)).

The Akopov et al. reference further fails to anticipate or render obvious the methods of the present invention insofar as such reference necessarily incorporates the use of a deployment apparatus for use in securing the subject surgical staples into position. As discussed above, and as further articulated in the accompanying declarations of Drs. Thomas, DeSantis, and Benderev, the present invention utilizes implants that can be manually inserted at a target site and do not require the use of any type of deployment device. Such capabilities enable the same to be rapidly deployed with far greater accuracy than prior art implants, in particular those that are the subject of the Akopov et al. reference. As discussed above, the declarations of Drs. Thomas, DeSantis, and Benderev submitted herewith clearly indicate that the methods and devices for securing sutures and the like to bone and tissue are more secure, easier to deploy and more desirable to utilize than such prior art devices, in particularly in light of the omission of the use of a


deployment device which typically must be utilized with prior art devices, such as those disclosed in the Akopov et al. reference.

Based on the foregoing amendment, remarks and declarations of Drs. Thomas, DeSantis, and Benderev submitted pursuant to 37 C.F.R. §1.132, Applicant respectfully submits that the claims, as amended, are allowable over the cited prior art. Similarly, New Claims 19-38, which are drawn to new embodiments disclosed in the present continuation-in-part patent application, are likewise believed to be allowable over the prior art. In this regard, such claims are directed to novel systems and methods for enabling a suture line to be secure within soft tissue at a desired target site. Such claims are likewise believed to be allowable over the cited prior art and Applicant respectfully requests early notice to that effect.

To the extent the Examiner has any questions, requires additional information or has any suggestions to resolve any outstanding issues that may remain, he is invited to contact Applicant's counsel at the number listed below.

Respectfully Submitted,

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